

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group:	1615	}
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Confirmation No.:	4549	}
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Application No.:	10/467,925	}
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Applicant:	Jean-Mane et al.	}
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Filed:	June 16, 2004	}
		}
Attorney docket:	16218-72987	}
		}
Examiner:	Hasan Syed Ahmed	}

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Jean-Michel HANNETEL, hereby declare as follows:

I am one of the inventors of the above-identified U.S. application.

I am responsible for Technological Development for V. MANE FILS, the assignee of the above-identified U.S. application.

I have read the Official Action mailed February 7, 2008, and I am familiar with the present application. In reviewing the Official Action, there does not appear to be an appreciation of the method steps utilized for forming the inventive capsules relative to the

comparative capsule in Example 2 of the present specification. The Official Action indicates the method steps are not indicated for this Example.

However, the inventive capsules were prepared according to disclosed and claimed method, and the method is described below:

Shell and core solutions used in capsule manufacturing process are prepared separately. Shell solution contains all water-soluble ingredients which are dissolved in water and then the solution is heated in 65°C before being processed. Core solution contains all oil soluble ingredients which are mixed at room temperature before being processed. In the example 2 for composition 1, the method is as follow: in a stainless steel beaker, dissolve in 770ml of water 4.5g of fumaric acid. Add 22.5g of sorbitol and 0.50g of allura red (FD&C Red 40), and stir until complete dissolution. Then pour into the solution, under mixing, 202.5g of gelatin (260A Pork gelatin from Rousselot). Place the beaker in a water bath at 65°C for 2 hours until a homogeneous liquid solution, which is totally degassed, is obtained.

Separately, prepare the core solution made of 25% of cinnamon flavor base, 5% of ethanol, 0.8% of sucralose and 69.2% of vegetal oil.

Both solutions are then pumped separately to a coaxial co-extrusion nozzle at appropriate flow rate to form cylinders which are cut into seamless spherical capsules under the action of vibration on the nozzle with a frequency of 9 capsules/sec. Targeted size of finished capsule is 5mm diameter. The core solution is carried to the nozzle at room temperature with a flow rate of 32.5ml/min. The shell solution is pumped to the nozzle with a flow rate of 13.5ml/min, maintaining the temperature in the pipe at 50°C. A Co-extrusion apparatus such as described in US patent US 5,387,093 can be used to obtain such capsules.

The capsules formed fall in a cooling tube filled with a vegetable oil maintained between 12 and 15°C. The drops circulated in this cooling circuit in order to gelify. Wet capsules are then collected in a basket and stored under cold temperature (+4°C) in vegetable oil for one hour.

After the one hour, the vegetable oil is separated from the capsules by soft centrifugation. Capsules are then washed in two separate ethanol bath for 5-10 minutes and are dried using dried air at 35°C in a coating pan.

Finally, capsules are sieved between 4.5mm and 5.5mm and are analyzed in term of dissolution time (liberation time and total dissolution time) as described in the present patent application.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Jean-Michel HANNETEL

July 7th, 2008

Date